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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,347	07/18/2000	HITOSHI ENDOU	49429	7848

7590 10/22/2002
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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/424,347

Applicant(s)

ENDOU ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group VI, claim 17 drawn to a method of screening for a compound to effect SEQ ID NO: 2 in Paper No. 8, 1/15/2002 is acknowledged. The traversal is on the ground(s) that the Groups are related and there is no burden to search. This is not found persuasive because the inventions are distinct as noted in Paper No. 6, 9/11/2001, as shown by the distinctness described therein. Applicant's attention is directed to MPEP 806.05. Contrary to applicants' assertion that any search of the prior art in regard to group VI will reveal whether any prior art exists as to the other Groups, a search is directed to references which would render the invention obvious, as well as references directed to anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The disclosure is objected to because of the following informalities: The words "Invention" and Carrying" are misspelled on page 3, line 15.

Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also

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embedded in the text of the description or claims of the patent application (MPEP 2422, 37 CFR 1.821). The Specification does not refer to the sequences as "SEQ ID NO: ", see e.g page 4, line 3; claim 1; and the Abstract of the Disclosure.

Appropriate correction is required.

Claim Objections

Claim 17 is objected to because of the following informalities: It contains subject matter drawn to a non-elected Group. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is vague and indefinite because it is not clear what "the substrate effect of tested compound to ability" means. It is presumed that this means to screen a compound for an effect on organic anion transport.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 17 is rejected under 35 U.S.C. 102(a) as being anticipated by Sweet et al. (1997).

Sweet et al. teaches that expression cloning in *Xenopus laevis* oocytes was used to isolate an organic anion transport protein from rat kidney. A 2, 227-base pair cDNA clone containing a 1,656-base pair open reading frame coding for a peptide 551 amino acids long was isolated and named ROAT1 (Sweet at 30091, Figure 3). ROAT1 is 87.0% identical to SEQ ID NO: 2 of the instant application (see Sequence Comparison A, attached), thus it falls within the limitation of claim 1 wherein the sequence has at least one substitution. The effects of several compounds on ROAT1 were assayed, including the organic cation tetraethylammonium, by the multidrug resistance ATPase inhibitor cyclosporin A, or by urate (Ibid at 30093, Figure 8). External glutarate and alpha-ketoglutarate (1 mM), both counterions for basolateral PAH exchange, also inhibited transport, suggesting that ROAT1 is functionally similar to the basolateral PAH carrier (Ibid. at 30094, Figure 9). Thus claim 17 is anticipated.

Claim 17 is rejected under 35 U.S.C. 102(a) as being anticipated by Sekine et al. (1997).

Sekine et al. teaches the isolation of a novel complementary DNA from rat kidney that encodes a 551-amino acid residue protein (OAT1) with 12 putative membrane-spanning domains. When expressed in *Xenopus laevis* oocytes, OAT1 mediated sodium-independent para-aminohippurate (PAH) uptake (Sekine at 18527, Figure 1). OAT1 is 87.0% identical to SEQ ID NO: 2 of the instant application (see Sequence Comparison A, attached), thus it falls within the limitation of claim 1 wherein the sequence has at least

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one substitution. The effects of several compounds on OAT1 were assayed including endogenous substrates such as cyclic nucleotides, a prostaglandin and uric acid, and a variety of drugs with different structures (e.g. antibiotics, a nonsteroidal anti-inflammatory drug, diuretics, an antineoplastic drug, and a uricosuric drug) (Ibid. at 18528, Figure 4). Thus claim 17 is anticipated.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
October 10, 2002